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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,074	11/19/2003	Richard J. Davies	DAVIES 3.0-001 CIP I	7252
530 7590 06/05/2008 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER SZMAL, BRIAN SCOTT	
			ART UNIT 3736	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/717,074	Applicant(s) DAVIES, RICHARD J.	
	Examiner Brian Szmaj	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-43 is/are pending in the application.
- 4a) Of the above claim(s) 13-36 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38-40 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-12, 37 and 41-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/29/08</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 6-10, 42 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Schulze et al (7,223,239 B2).

Schulze et al disclose a device that removably attaches to an organ and further disclose a housing having an interior space; an electrode positioned within the interior space of the housing; the housing includes a first opening communicating with the interior space of the housing and adapted to be placed substantially proximate to the surface of the region of tissue; the housing including a second opening communicating with the interior space of the housing; when the first opening is placed substantially proximate to the surface, an electroconductive medium is disposed within the interior for facilitating an electrical connection between the region of tissue and the electrode and suction is applied to the second opening, an electrical connection is made between the region of tissue and the electrode via the electroconductive medium; the device is suitable for determining the condition of a region of tissue; a flange surrounding the first opening; the region of tissue has ducts; the region of tissue is selected from the tissue group consisting of breast, prostate, liver, uterus, pancreas and salivary gland tissue; a

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measuring device in communication with the electrode operable to determine an electrical signal from the electrode; a displaying device in communication with the measuring device operable to display the electrical signal from the electrode; and the tissue is epithelium containing tissue. See Column 5, lines 60-66; Column 6, lines 34-41; Column 7, lines 20-25 and 32-33; and Column 11, lines 34-41.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 5 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al (5,109,849) in view of Meathrel et al (5,833,622).

Goodman et al disclose a sensor assembly and further disclose a cup having an interior, and first and second openings; a current passing electrode disposed within the interior; a source of suction connectable to the first opening; when the second opening is placed over a region of tissue, an electroconductive medium is disposed within the interior and suction is applied to the first opening; the electroconductive medium is a saline solution; and the tissue is epithelium containing tissue. See Column 7, lines 39-50; Column 8, lines 4-8; and Column 12, lines 27-30.

Goodman et al however fail to disclose an electroconductive medium is disposed within the interior for facilitating an electrical connection between the region of tissue to

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be examined and the electrode, and an electrical connection is made between the region of tissue and the electrode via the electroconductive medium.

Meathrel et al disclose a non-invasive probe and further disclose an electroconductive medium is disposed within the interior for facilitating an electrical connection between the region of tissue to be examined and the electrode, and an electrical connection is made between the region of tissue and the electrode via the electroconductive medium. See Column 1, lines 24-28; Column 9, lines 62-64; and Column 10, lines 11-13.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Goodman et al to provide an electrode that utilizes an electroconductive medium for an electrical connection between the tissue and the electrode, as per the teachings of Meathrel et al, since it is well known in the art that a sensing electrode can be placed directly on a tissue surface, or the electrode can comprise an electroconductive medium between the electrode and the tissue surface.

5. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al (5,109,849) and Meathrel et al (5,833,622) as applied to claim 1 above, and further in view of Hirsch et al (5,345,935).

Goodman et al and Meathrel et al, as discussed above, disclose a sensing device, but fail to disclose the suction source is a syringe or an aspirator.

Hirsch et al disclose a suction based medical probe and further disclose the suction source is a syringe or an aspirator. See Figures 6-11.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Goodman et al and Meathrel et al to include the use of a syringe or aspirator for a suction source, as per the teachings of Hirsch et al, since it is well known in the art to use a syringe or an aspirator for a vacuum source.

6. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulze et al (7,223,239 B2) as applied to claim 10 above, and further in view of Dempsey et al (5,417,222).

Schulze et al, as discussed above, disclose a means for applying a device to tissue, but fail to disclose the measuring device is in communication with the electrode by a wireless connection; the displaying device is in communication with the measuring device by a wireless connection.

Dempsey et al disclose a patient monitoring system and further disclose the measuring device is in communication with the electrode by a wireless connection; the displaying device is in communication with the measuring device by a wireless connection. See Figure 1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Schulze et al to include the use of a wireless connection, as per the teachings of Dempsey et al, since it is well known in the art to substitute a wireless connection for a wired connection in medical applications.

7. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al (5,109,849) and Meathrel et al (5,833,622) as applied to claim 1 above, and further in view of Schulze et al (7,223,239 B2).

Goodman et al and Meathrel et al, as discussed above, disclose a sensing device, but fail to disclose the use of a pharmacological agent in combination with the electroconductive medium.

Schulze et al, as discussed above, disclose a means for applying a device to tissue and further disclose the use of a pharmacological agent in combination with the electroconductive medium. See Column 9, lines 42-45.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Goodman et al and Meathrel et al to include the use of a pharmacological agent, as per the teachings of Schulze et al, since it would provide a means of applying a therapy to the measurement site.

Allowable Subject Matter

8. The following is a statement of reasons for the indication of allowable subject matter: Claims 38-40 are allowable due to the incorporation of previously allowed subject matter in an independent claim.

Response to Arguments

9. Applicant's arguments, filed January 25, 2008, with respect to the rejection(s) of claim(s) 1, 5 and 41 under Goodman et al (5,109,849) have been fully considered and

are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Goodman et al (5,109,849) in view of Meathrel et al (5,833,622).

10. Applicant's arguments filed January 25, 2008 have been fully considered but they are not persuasive.

The Applicant argues Schulze et al fail to disclose the elements of Claims 6 and 10, because Schulze et al is used for ablating tissue and not providing a measurement relating to the tissue. Schulze et al clearly discloses the device can be used for diagnosing tissue conditions (see Column 7, lines 20-23).

The Applicant further argues Schulze et al fail to disclose an electroconductive medium. This is also incorrect. Schulze et al clearly discloses the use of saline in Column 7, lines 32-33, when used in conjunction with EMG transducers disclosed in Column 7, lines 20-23. Saline, per the Applicant's disclosure is an electroconductive medium, and therefore Schulze et al also discloses an electroconductive medium.

The Applicant further argues there is no disclosure of "a measuring device in communication with the electrode operable to determine an electrical signal from the electrode" in Schulze et al. The disclosure of an EMG transducer in Column 7, lines 20-23, inherently discloses a measuring device in communication with the EMG transducer.

The Applicant further argues Schulze et al fail to disclose the claimed elements of Claim 37. Schulze et al, as discussed above, clearly disclose the use of an electroconductive medium (108) (saline), and further disclose in Column 9, lines 42-45,

the use of therapeutic agents in fluid (108). Therefore, Schulze et al clearly discloses the claimed elements of Claim 37.

The Applicant further argues Schulze et al fail to disclose a means suitable for determining the condition of a region of tissue. As discussed above, Schulze et al clearly discloses the use of EMG transducers, which determine the condition of tissue.

The Applicants further argue Schulze et al, in combination with Dempsey et al fail to cure the deficiencies of Schulze et al, because a wireless connection cannot be used with the means of Schulze et al. The Examiner disagrees. As discussed above, Schulze et al clearly discloses the use of EMG transducers. It is well known in the art to utilize wired or wireless connections for acquiring EMG signals from a patient. Therefore, the rejection of Claims 11 and 12 stand.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmalec whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmalec/
Patent Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736

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